

Notice of Allowability

Application No.

09/980,862

Examiner

Samuel W. Liu

Applicant(s)

SCHLEHUBER, STEFFEN

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/25/05.
2. ☒ The allowed claim(s) is/are 1-7, 18 and 19.
3. ☒ The drawings filed on 07 December 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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DETAILED ACTION

Applicants' amendments filed 2/25/05 which amends claims 1-7 and 15, adds claims 18-21 has been entered. Claims 8-17 are withdrawn from further consideration by the examiner (see the Office action mailed 8/26/04). Also, the applicants' request (filed 2/25/05) for extension of time of three months has been entered. Thus, the pending claims 1-7 and 18-21 are examined in this Office action.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Alexey Sapritin on behalf of Stephen B. Maebius on July 26, 2005. Applicants agree to the examiner proposed amendment to claims 1, 3, 6 (see below).

Amendments to the claims:

Claim 1 (*Amended*): An isolated mutein of the bilin-binding protein of *Pieris Pieris brassicae* wherein said mutein

- (a) is able to bind digoxigenin or digoxigenin conjugates,
- (b) does not bind ouabain, testosterone or 4-aminofluorescein and,
- (c) has an amino acid substitution at one or more of the sequence positions residues 28, 31, 34, 35, 36, 37, 58, 60, 69, 88, 90, 95, 97, 1, 14, 116, 125, and 127 of the wild type bilin binding protein (SEQ ID NO: 28).

Claim 3 (*Amended*): The mutein according to claim 1, wherein said mutein carries, in comparison with the wild type bilin-binding protein (SEQ ID NO: 28), at least one of the amino acid substitutions selected from the group consisting of Glu(28) → Gln, Lys (~~31~~) (31) → Ala, Asn(34) → Asp, Ser(35) → His, Val(36) → Ile, Glu(37) → Thr, Asn(58) → Arg, His(60) → Ser, Ile(69) → Ser, Leu(88) → Tyr, Tyr(90) → Ile, Lys(95) → Gln, Asn(97) → Gly, Tyr (114) → Phe, Lys (116) → Ser, Gln(125) → Met, and Phe(127) → Leu.

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Claim 6 (*Amended*): A fusion protein comprising the mutein of claim 1, wherein a fusion partner of said fusion protein comprises at least one member selected from the group consisting of an enzyme, a protein, a protein domain, a signal sequence and ~~an affinity peptide~~ a peptide that facilitates purification and/or detection of said fusion protein and wherein the fusion partner is fused to the amino terminus of the mutein.

Claim 7 (*Amended*): A fusion protein comprising the mutein of claim 1, wherein a fusion partner of said fusion protein is at least one member selected from the group consisting of an enzyme, a protein, a protein domain, a targeting sequence and ~~an affinity peptide~~ a peptide that facilitates purification and/or detection of said fusion protein, wherein said targeting sequence allows the transport of the fusion protein into a specific cell, and wherein the fusion partner is fused to the carboxy terminus of the mutein.

Delete claims 8-17.

Claim 18 (*Amended*): The fusion protein according to claim 6, further comprising a second fusion partner that is at least one member selected from the group consisting of an enzyme, a protein, a protein domain, a targeting sequence which allows the transport of the fusion protein in a specific cell compartment and ~~an affinity peptide~~ a peptide that facilitates purification and/or detection of said fusion protein and wherein this second fusion partner is fused to the carboxy terminus of the mutein of the bilin binding protein.

Claim 19 (*Amended*): The fusion protein according to claim 7, further comprising a second fusion partner that is at least one member selected from the group consisting of characterized in that an enzyme, another a protein, or a protein domain, a signal sequence and/or ~~an affinity peptide~~ a peptide that facilitates purification and/or detection of said fusion protein and wherein this second fusion partner is fused to the amino terminus of the mutein of the bilin binding protein ~~polypeptide~~.

Delete claims 20 and 21.

Amendments to the specification:

On page 18, line 35 before "Figure 1 shows" and in a separate line, add "Brief Description of the Drawings".

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The following is an **Examiner's Statement of Reasons for Allowance**:

The prior art of record does not show or fairly suggest the claimed mutein consisting of the sequence of SEQ ID NO:28 (encoded by the nucleotide sequence of SEQ ID NO:15) which is free from the prior art has the biological activities set forth in instant claim 1; and thus, the substitution mutations of the SEQ ID NO:28 mutein protein is allowable. Examiner has noted that WO 99/16873 teaches that the polypeptide encoded by SEQ ID NO:10 polypeptide is subject to amino acids substitutions, and that the SEQ ID NO:28 (174 amino acids) of the instant claim 1 is a subsequence of the SEQ ID NO:10 polypeptide (375 amino acids) of WO 99/16873. Hence, 99/16873 patent is not considered to be the prior art over the current invention since the current invention is directed to substitution mutation of SEQ ID NO:28 protein.

New claims 18-19 are drawn into the claimed protein; and thus, claims 1-7 together with claims 18-19 are directed to an allowable product whereas the new claims 20-21, which depend from claim 15, i.e., a process claim comprising use of the nucleic acid (for a *mutagenesis*) to preparing mutein of the bilin-binding protein, are not. Since the current invention is directed to the protein but not the nucleic acid (they are patentably distinct products), claim 15 and the claims dependent thereto are drawn to different/distinct inventions from the invention being drawn to the claimed mutein protein (see the restriction requirement mailed 5/26/04).

Therefore, the pending claims 1-7 and 18-19 are allowed.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jon Weber, can be reached at (571) 272-0925. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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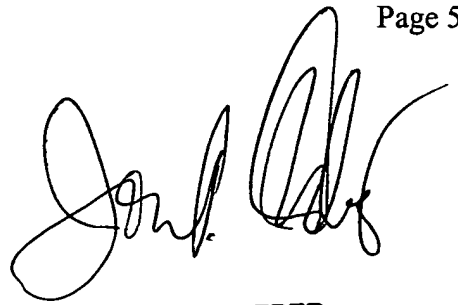
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A handwritten signature in black ink, appearing to be 'SWL' with a stylized flourish at the end.

Samuel W. Liu, Ph.D.

Patent Examiner, AU 1653

July 27, 2005

A handwritten signature in black ink, appearing to be 'Jon Weber' with a large, stylized 'J' and 'W'.

JONWEBER
SUPERVISORY PATENT EXAMINER